UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION

Case No. 1:14-CV-01748
MDL 2545

JUDGE MATTHEW F. KENNELLY

REPLY IN SUPPORT OF MOTION OF DEFENDANTS ABBVIE INC. AND ABBOTT LABORATORIES PURSUANT TO THE COURT'S JUNE 15, 2015 AMENDED CMO 14 TO ASSURE THE FINALITYAND INTEGRITY OF THE BELLWETHER POOL

Plaintiffs' Opposition makes inaccurate assumptions about the bellwether process, downplays the significant discovery failures that persist, and fails to appreciate the complexity of the 184 cases involving other manufacturer's TRT products. The Court should dismiss Plaintiffs who have failed to comply with basic discovery obligations, despite repeated chances, to ensure the bellwether pool is complete and populated with Plaintiffs ready and able to litigate their claims. The Court should also exclude those cases where the Plaintiff took multiple manufacturers' TRTs, which will limit the pool to truly representative "AbbVie-only" cases, and will avoid injecting complicating factors into the first round of bellwether discovery and potential trials.

ARGUMENT

I. It is Timely and Necessary To Dismiss The Claims Of Any Plaintiff Who Fails To Cure Discovery Deficiencies By August 14, 2015.

Plaintiffs' position rests on inaccurate and premature assumptions about the bellwether selection process. On August 10, 2015, the parties will submit proposals for selecting bellwether cases for pretrial discovery, motion practice, and potential trial. As Amended CMO 14 makes clear, the parties must "identify[] the process and parameters for selecting AbbVie-only bellwether plaintiffs," to "maximize the likelihood that the bellwether selection and trial process will be both representative and productive." Amended CMO 14 at 1-2. It is the Court that then

decides what the process will be. Plaintiffs' Opposition presumes the proposals and the Court's decision will be little more than a formality because the "process" will be simply to delegate selection to the parties. Pls.' Opp. at 2-3. But that presumption conflicts with the CMO, with the Court's proper role as the transferee court, with the Court's repeated direction that representative cases should be selected, and is certainly not what AbbVie will suggest in its August 10 proposal. Of particular relevance to the motion at issue, the parties and the Court will need to know what the AbbVie-only pool looks like, both before August 30 when the Court decides the selection process and immediately thereafter when that decision is implemented.

It is for these very reasons that AbbVie has repeatedly pressed the necessity of having properly completed PFSs as soon as practicable and the Court has responded by setting deadlines for completion. While AbbVie fully takes to heart the Court's caution that perfection can be the enemy of the good, the deficiencies on which AbbVie has moved go right to the test of completion under Amended CMO 9: "substantial completion" is reached when all of the questions have been answered. Indeed, AbbVie has focused its motion on a subset of questions that have unquestionable significance but were not answered. There can be no question but that they should be answered and no reason why those answers should not have been given by June 15 at the latest, particularly given that Plaintiffs already received multiple extensions of time.

Plaintiffs advance three arguments to urge that tardy claimants be given yet another extension. First, they insist that the deficiency letter process included in Amended CMO 9 still must be followed. This contention is directly contrary to the Court's decision to set the deadlines called out in the March 3 and May 29 amendments, both of which set dates for "completion" of the PFS, not for the commencement of a letter writing process. The deficiency letter process was

set long ago in the original CMO 9.[1] It was not a gateway for the extension of the Court's more recently imposed deadlines. What is more, AbbVie's proposed August 14 deadline is not far different from the time periods applicable to the deficiency letter process.

Plaintiffs also argue that the outstanding PFS deficiencies are "immaterial" and easily cured. If that is the case, Plaintiffs can cure the outstanding issues before August 14 and resolve this issue. Relatedly, Plaintiffs urge that the deficiencies are now already in the process of being cured. Accepting Plaintiffs' representations,[2] there were 184 deficiencies as of July 6, 2015, when AbbVie filed this Motion. Unsurprisingly, the filing spurred Plaintiffs to action and a majority have since cured the outstanding deficiencies. But AbbVie's Motion was the necessary catalyst that spurred those delinquent Plaintiffs to comply with the Court's discovery Order. In fact, the course of this litigation over the last five months has demonstrated that many Plaintiffs act ***only*** when threatened by Court intervention.

And then there is the central concern that drives the need for a final deadline, a concern that Plaintiffs treat too lightly. The concern relates to the integrity of the bellwether pool. Going forward, it is crucial that the pool be comprised of claimants who will have the diligence required of litigants under the rules. The creation of an MDL does not diminish that requirement in any way. Indeed, any diminution would directly undercut the Court's ability to manage the case, for the simple and obvious reason that tolerating non-compliance will inevitably result in

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[1] Earlier this year, circumstances had changed and warranted a revision to the existing procedure. As the Federal Manual for Complex Litigation notes, "active case management is imperative" and a judge "must . . . updat[e] and modify[] [case management orders] as the litigation unfolds." MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.6 (2004) (emphasis added). Where a case management order no longer furthers the goals of producing an efficient and just result, it requires modification by the Court.

[2] AbbVie does not agree with Plaintiffs' assertion that 83 deficiencies were listed incorrectly.

claimants who are unwilling to furnish timely discovery dropping their cases or seeking exclusion if they are selected to be bellwethers. A final hard deadline of August 14, 2015 to comply with this Court's basic discovery requirement is both fair and necessary to ensure Plaintiffs submit the necessary information in advance of bellwether selection, and to finally determine the composition of the pool.

Third, Plaintiffs' Opposition contains extensive discussion about medical authorizations, claiming that AbbVie is not currently using them and musing that Plaintiffs should therefore no longer be forced to provide authorizations. This argument is premature and meritless. Once the Court selects the 32 cases for bellwether discovery and pretrial practice, it will be essential to begin medical record collection immediately to meet the Court's discovery schedule. Absent proper authorizations, bellwether discovery cannot begin and a case cannot be eligible for selection.

II. The Court Should Limit The AbbVie-Only Bellwether Pool To Cases That Involve Only AndroGel.

The Court and the parties agreed months ago that the first bellwether cases would be "AbbVie-only." That decision impacted the schedule entered by the Court, which neither includes any provision for conducting discovery of other manufacturers, nor allows for the participation of those manufacturers in the bellwether process or resolution of legal issues arising from their participation. As a result, there can be no serious argument that the "AbbVie-only" cases should include Plaintiffs who used both AndroGel and another manufacturer's TRT. AndroGel-only cases comprise almost 75% of the bellwether pool, and are surely more representative, and more straightforward, than cases with additional product use. Despite this, Plaintiffs would have the Court muddy the pool by including cases that are more factually and

legally complicated because they involve Plaintiffs who were prescribed and used multiple TRTs. The Court should not do so for three reasons.

First, Plaintiffs' Opposition does not dispute that the parties agreed to defer generic discovery of the other TRT Defendants at the same time they determined that the bellwether program would litigate "AbbVie-only" cases. The Court's schedule does not allow for the participation of other manufacturers in "AbbVie-only" cases, and had Plaintiffs intended to pursue cases where multiple Defendants' products (and their warnings) were at issue, they should not have agreed to these restrictions. This is true even for those Plaintiffs who chose not to sue a potential Defendant for tactical reasons. More generally, Plaintiffs simply miss the principal relevance of non-AndroGel use. The relevance lies not only in its potential impact on causation, but in its significance to the warnings side of the case. Use of a non-AbbVie TRT will potentially include different prescribers, different marketing, and variations in warnings. All of this needs to be explored through additional case-specific discovery and at trial. It is easy for Plaintiffs to dismiss the significance of these additional facts, because they will not have the burden of the additional pretrial and trial work that is entailed in dealing with the facts related to non-AbbVie products.

Second, Plaintiffs' reliance on the *Yasmin and YAZ*, *Ortho Evra*, and *NuvaRing* litigations is misplaced. AbbVie is not, as Plaintiffs' claim, arguing that a Plaintiff was obligated to sue the manufacturer of each TRT product he ever used. But Plaintiffs who were prescribed other TRTs are not ***representative*** in a bellwether program designed to test the viability of claims against ***AbbVie*** and premised on use of AndroGel alone. *See Standards and Best Practices for*

Large and Mass-Tort MDLs 27 (2014) ("[T]he key is to select cases that are representative of the entire claimant pool (or of specific categories in that pool).").[3]

As noted above, including cases that involve other, non-AbbVie TRT use would lead to an unrepresentative case-specific discovery and trial process. By agreeing to proceed with AbbVie-only cases, the decision was already made to proceed without other manufacturers, who would otherwise participate fully if sued in a multi-Defendant case. Including non-AbbVie TRT use cases in the AbbVie-only bellwethers, without the full benefit (and defense) of those other products also would unnecessarily complicate the pretrial process and weaken the predictive value of any rulings or trial results.

Moreover, the circumstances presented in the birth defect litigations referenced by Plaintiffs were plainly different. For example, both *In re Ortho Evra Prods. Liab. Litig.* MDL 1742 (N.D. Ohio) and *In Re: Nuvaring Prods. Liab. Litig.*, MDL No. 1964 (E.D. Mo.) involved only one medication—the Ortho Evra contraceptive patch and NuvaRing contraceptive vaginal ring, respectively. This is plainly different than the TRT litigation, where multiple products are at issue.[4] In *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Products Liab. Litig.*, the first round of bellwether cases allowed for the participation of multiple defendants.[5] Yet, as the *Yaz* court recognized, this initial multi-defendant "bellwether process . . . completely broke[]

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[3] Available at: https://law.duke.edu/sites/default/files/centers/judicialstudies/MDL_Standards_and_Best_Practices_2014-REVISED.pdf.

[4] While there were multiple defendants involved in both litigations, the majority were corporate affiliates or predecessors in interest of the primary defendant.

[5] *See In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Products Liab. Litig.*, MDL 2100, Amended Case Management Order No. 24 at 7-8 (Oct. 13, 2010) (attached as Ex. 1).

down."[6] The court's revised bellwether program recognized that it had to separate the cases involving one manufacturer's product from the cases involving multiple product use.[7] The Court should follow suit here and limit the first phase of the litigation to claims involving AndroGel.

Third, Plaintiffs' argument minimizes the tactical prejudice to AbbVie, the other Defendants, and the Court's schedule that would result if the pool were to include cases where the Plaintiff used multiple TRT products. To gain a tactical advantage at this stage, Plaintiffs suggest there is no harm because AbbVie can "point to the empty chair." Yet there is no question that if a case involving absent TRT manufacturers survived to trial, Plaintiffs would do everything in their power to prevent AbbVie from mentioning that other TRT use. Of course, the Plaintiff would be judicially estopped from making such an argument, having taken a contrary position in the Opposition to this Motion. But even if AbbVie is permitted to "point to the empty chair" without restriction, there is no benefit to the bellwether process for a jury to in any way base their decision on AbbVie's liability based on the warning and/or scientific impact of a TRT product manufactured by undefended "empty chair." Likewise, such a result serves little to no predictive value of any rulings or trial results for either true AbbVie-only cases or multi-Defendant cases.

CONCLUSION

For the reasons set forth above, AbbVie respectfully requests this Court to dismiss with prejudice the claims of those Plaintiffs who fail to cure all identified PFS deficiencies by August

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[6] *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Products Liab. Litig.*, MDL 2100, Amended Case Management Order No. 54 at 2 (Jan. 10, 2012) (attached as Ex. 2).

[7] *See In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Products Liab. Litig.*, MDL 2100, Amended Case Management Order No. 65 at 4 (Aug. 28, 2014) (attached as Ex. 3).

14, 2015. AbbVie also respectfully requests this Court to exclude from the initial "AbbVie-only" bellwether pool those Plaintiffs who admit they used TRTs other than AndroGel.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christopher R. Boisvert, hereby certify that on July 31, 2015, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Christopher R. Boisvert